K130250

MAY 3 2013

510(k) Summary
QYAG Laser Handpiece

This 510(k) summary is being submitted in accordance with 21 CFR 807.92

1. SUBMITTER'S INFORMATION

NAME: Palomar Medical Technologies, Inc.

ADDRESS: 15 Network Drive
Burlington, MA 01803
Phone: (781) 993-2348
Fax: (781) 993-2330

CONTACT: Nicole Brown
Regulatory Affairs Specialist II

DATE PREPARED: January 21, 2013

2. DEVICE INFORMATION

TRADE/PROPRIETARY NAME: Palomar QYAG Laser Handpiece

COMMON/USUAL NAME: Q: SWITCHED : Nd:YAG laser

CLASSIFICATION NAME: Laser surgical instrument for use in general and plastic surgery and in dermatology.
(21 CFR §878.4810)

PRODUCT CODE: GEX

3. PREDICATE DEVICES

Palomar Medical Technologies, Inc.
PALOMAR Q-YAG 5 ND:YAG LASER SYSTEM
K061436

HOYA ConBio, Inc.
RevLite Q-Switched Nd:YAG Laser System

K083899

Quanta System SPA
Q-PLUS T+ IPL LASER SYSTEM
K123168

Lutronic Corporation
Spectra Laser System
K113588

4. INTENDED USE

The Palomar QYAG Laser Handpiece is indicated at the 1064 nm wavelength for dark (i.e. dark blue or black) ink tattoo removal, removal of pigmented lesions, including but not limited to, lentigines, nevi, melasma, Becker Nevus, Nevus-of-Ota and Café-au-Lait birthmarks. The 532 wavelength is indicated for the removal of light (red, orange, yellow or green) ink tattoos and most pigmented lesions (e.g. lentigines, ephlides). The 1064/532 blended wavelength is indicated for tattoo removal.

5. DEVICE DESCRIPTION

The QYAG Laser handpiece is an accessory to the Palomar ICON System, which is composed of a system console, cooling system, power supply and handpiece. Laser energy is produced in the handpiece and delivered directly to the tissue.

6. PERFORMANCE DATA

The specifications and indications for use of the QYAG Laser are substantially equivalent to its predicate devices. Thus, do not result in additional safety or effectiveness information.

7. SUBSTANTIAL EQUIVALENCE

The QYAG Laser Handpiece is substantially equivalent to its predicate devices when used according to its intended use. The information that is provided in this application demonstrates that the QYAG Laser also shares the same technological characteristics as its predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Palomar Medical Technologies, Inc.
% Ms. Nicole Brown
Regulatory Affairs Specialist II
15 Network Drive
Burlington, Massachusetts 01803

May 3, 2013

Re: K130250
Trade/Device Name: Palomar QYAG Laser Handpiece
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 01, 2013
Received: March 04, 2013

Dear Ms. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,
For

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130250

Device Name: QYAG Laser System

The Palomar QYAG Laser Handpiece is indicated at the 1064 nm wavelength for dark (i.e. dark blue or black) ink tattoo removal, removal of pigmented lesions, including but not limited to, lentigines, nevi, melasma, Becker Nevus, Nevus-of-Ota and Café-au-Lait birthmarks. The 532 wavelength is indicated for the removal of light (red, orange, yellow or green) ink tattoos and most pigmented lesions (-e.g. lentigines, ephlides). The 1064/532 blended wavelength is indicated for tattoo removal.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.05.08 15:49:47 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number __K130250_____